

§ 460.54

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agency in writing about termination and transition procedures.

(2) Assist participants to obtain reinstatement of conventional Medicare and Medicaid benefits.

(3) Transition participants' care to other providers.

(4) Terminate marketing and enrollment activities.

(b) An entity whose PACE program agreement is in the process of being terminated must provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and making the participant's medical records available to new providers.

§ 460.54 Termination procedures.

(a) Except as provided in paragraph (b) of this section, if CMS terminates an agreement with a PACE organization, it furnishes the PACE organization with the following:

(1) A reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of CMS's determination that cause exists for termination.

(2) Reasonable notice and opportunity for hearing (including the right to appeal an initial determination) before terminating the agreement.

(b) CMS may terminate an agreement without invoking the procedures described in paragraph (a) of this section if CMS determines that a delay in termination, resulting from compliance with these procedures before termination, would pose an imminent and serious risk to the health of participants enrolled with the organization.

Subpart E—PACE Administrative Requirements

§ 460.60 PACE organizational structure.

(a) A PACE organization must be, or be a distinct part of, one of the following:

(1) An entity of city, county, State, or Tribal government.

(2) A private not-for-profit entity organized for charitable purposes under section 501(c)(3) of the Internal Revenue Code of 1986. The entity may be a corporation, a subsidiary of a larger

corporation, or a department of a corporation.

(b) *Program director.* The organization must employ, or contract with in accordance with § 460.70, a program director who is responsible for oversight and administration of the entity.

(c) *Medical director.* The organization must employ, or contract with in accordance with § 460.70, a medical director who is responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight, of the quality assessment and performance improvement program.

(d) *Organizational chart.* (1) The PACE organization must have a current organizational chart showing officials in the PACE organization and relationships to any other organizational entities.

(2) The chart for a corporate entity must indicate the PACE organization's relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entities.

(3) A PACE organization planning a change in organizational structure must notify CMS and the State administering agency, in writing, at least 14 days before the change takes effect.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71334, Dec. 8, 2006]

§ 460.62 Governing body.

(a) *Governing body.* A PACE organization must be operating under the control of an identifiable governing body (for example, a board of directors) or a designated person functioning as a governing body with full legal authority and responsibility for the following:

(1) Governance and operation of the organization.

(2) Development of policies consistent with the mission.

(3) Management and provision of all services, including the management of contractors.

(4) Establishment of personnel policies that address adequate notice of termination by employees or contractors with direct patient care responsibilities.

(5) Fiscal operations.

(6) Development of policies on participant health and safety, including a

comprehensive, systemic operational plan to ensure the health and safety of participants.

(7) Quality assessment and performance improvement program.

(b) *Participant advisory committee.* (1) A PACE organization must establish a participant advisory committee to provide advice to the governing body on matters of concern to participants. Participants and representatives of participants must constitute a majority of the membership of this committee.

(2) The participant advisory committee must provide the liaison to the governing body with meeting minutes that include participant issues.

(c) *Participant representation on the governing body.* (1) A PACE organization must ensure participant representation on issues related to participant care. This shall be achieved by having a participant representative on the governing body.

(2) The participant representative is a liaison of the participant advisory committee to the PACE organization governing body.

(3) *Duty of the participant representative.* The participant representative must present issues from the participant advisory committee to the governing body.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006]

§ 460.64 Personnel qualifications for staff with direct participant contact.

(a) *General qualification requirements.* Each member of the PACE organization's staff that has direct participant contact, (employee or contractor) must meet the following conditions:

(1) Be legally authorized (for example, currently licensed, registered or certified if applicable) to practice in the State in which he or she performs the function or action;

(2) Only act within the scope of his or her authority to practice;

(3) Have 1 year of experience with a frail or elderly population;

(4) Meet a standardized set of competencies for the specific position description established by the PACE organization and approved by CMS before working independently.

(5) Be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact.

(b) *Federally-defined qualifications for physician.* In addition to the qualification specified in paragraph (a) of this section, a physician must meet the qualifications and conditions in § 410.20 of this chapter.

[71 FR 71334, Dec. 8, 2006]

§ 460.66 Training.

(a) The PACE organization must provide training to maintain and improve the skills and knowledge of each staff member with respect to the individual's specific duties that results in his or her continued ability to demonstrate the skills necessary for the performance of the position.

(b) The PACE organization must develop a training program for each personal care attendant to establish the individual's competency in furnishing personal care services and specialized skills associated with specific care needs of individual participants.

(c) Personal care attendants must exhibit competency before performing personal care services independently.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006]

§ 460.68 Program integrity.

(a) *Persons with criminal convictions.* A PACE organization must not employ individuals or contract with organizations or individuals—

(1) Who have been excluded from participation in the Medicare or Medicaid programs;

(2) Who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under title XX of the Act; or

(3) In any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse.

(b) *Direct or indirect interest in contracts.* The PACE organization shall identify members of its governing body or any immediate family member having a direct or indirect interest in any